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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,046	09/25/2006	Nnochiri N. Ekwuribe	014811-673.119US	8968

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
11/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/594,046	EKWURIBE ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The previous indication of finality is withdrawn.

A Response filed October 10, 2008 is acknowledged. Claims 1-30 remain under consideration.

Following an amendment to claim 30, the objection set forth in the last Office Action is withdrawn.

A complete list of all co-pending and related application for the inventor Nnochiri Ekwuribe is requested when Applicants respond to this Office Action.

Claims 16-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claims 16-29 recite limitations "a" “b” and “c” relating to the pharmaceutical composition of claim 15. There is insufficient antecedent basis for these limitations in claim 15 from which claims 16-29 depend. Claim 15 is drawn to the pharmaceutical composition of claim 1 in which the formulation releases at least one component of part (a), (i) or (ii), and part (b). However, dependent claims 16-29 recite part (c) for which antecedent basis in claim 15 is absent.

Further, claims 16-29 are dependent from claim 15 which is dependent from claim 1. Claims 16-19 recite in part (a), “a 5-ASA compound.” Claims 20-23 recite in part (a), “a 4-APAA compound.” Parts (b) and (c) in claims 16-29 variously recite “a 5-ASA compound” and/or “a 4-APAA compound.” There is insufficient antecedent basis for these limitations in claim 1 because claim 1 is limited to an **azo-bonded** 4-APAA or 5-ASA compound, **non-azo bonded** 4-APAA or 5-ASA compound and a 4-APAA

compound **azo bonded** to a 5-ASA compound. Thus dependent claims 16-29 do not find clear antecedent basis in claim one.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-14 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed, had possession of the claimed invention. This is a Written Description rejection.

Although the specification provides Examples and discussion directed to the administration of oral formulations, there is insufficient written description for the employment of any dosage form in which another mode of administration is contemplated. Claims 8-14 are respectively drawn to a suppository, an enema, a mouth wash, and formulations for vaginal, intra-uterine, topical and eye administration. Claim 30 recites "treating an inflammatory colon condition."

MPEP § 2163 states "An Applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formulas that fully set forth the claimed invention… one must define a compound by 'whatever characteristics sufficiently distinguish it'. A lack of adequate written description issue also arises if the knowledge

and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process."

Considering the established efficacy of 4-aminophenylacetic acid compounds (as taught in U.S. Patent 6,583,128, for example), the present specification fails to provide an adequate written description for modes of administration and dosage forms other than via oral administration of tablets or capsules. As such, Applicants were not in possession of such dosage forms and modes of administration as recited in claims 8-14 at the time the invention was made.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, 15 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sandborn et al., U.S. Patent 6,166,044.

Sandborn teaches the concomitant administration of nicotine and agents that are known in the gastroenterology art to be efficacious in the treatment of inflammatory bowel diseases (IBD) through oral or rectal administration. Agents such as 5-ASA, sulfasalazine, alsalazine, as well as steroids, such as prednisolone or budesonide, are established agents for treating IBD. See column 8, lines 19-32. Delivery to the ileum and intestine is controlled through the employment of enteric coated dosage forms that enable the dosage form to remain intact while passing through the stomach.

The open language of the present claims allows for the addition of any number of other active or inactive ingredients.

Because Sandborn teaches a synergistic effect may be achieved through the administration of multiple active drugs, one skilled in the art of formulation chemistry would have been motivated to prepare and administer to a patient in need of treatment for an inflammatory disease of the colon, a pharmaceutical composition comprising non-azo bonded 5-ASA and an azo-bonded 5-ASA compound, such as sulfasalazine. Such would have been obvious in the absence of evidence to the contrary because Sandborn teaches a synergistic effect through the simultaneous administration of multiple agents that are known in the gastroenterology art to be effective in the treatment of inflammatory bowel diseases.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 15, 2008

/Phyllis G. Spivack/

Primary Examiner, Art Unit 1614